

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

HELM, et al.

Appln. No.: 09/133,766

Confirmation No.: 6988

Filed: August 12, 1998

For: ALLERGEN/INFLAMMATORY TESTING AND DIAGNOSIS

**SUBMISSION OF EXECUTED DECLARATION UNDER 37 C.F.R. §1.132**

Commissioner for Patents  
Washington, D.C. 20231

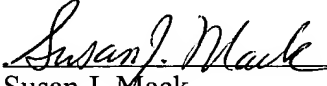
Sir:

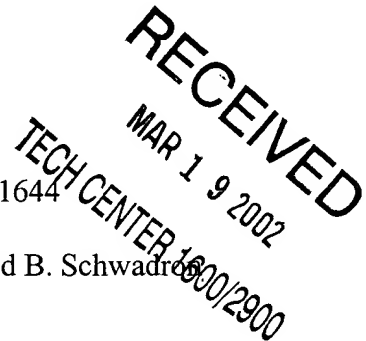
Submitted herewith is an executed Declaration Under 37 C.F.R. §1.132 signed by Brigit Helm.

Respectfully submitted,

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#20  
w/attachment



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In re the Application of

Birgit HELM (EURO DPC)

Serial no: 09/133,766 (Continuation)

Filed 25 November 1993

Signed: See below

Date: See below

I, Birgit Helm, declare that my credentials are as listed in the attached curriculum vitae:

I understand that the above Application, of which I am the inventor, is pending before the US Patent and Trade Mark Office and that an objection remains outstanding.

I understand the objection can be paraphrased as follows:

35 U.S.C. 112: The application does not contain subject matter described in a way as to reasonably convey to one skilled in the art the claimed invention. The examiner considers there is no support for the claims, or more specifically, there is no disclosure that the invention can be practised with any mast cell or basophil cell line.

In my opinion the invention can be practised using a wide variety of cell lines of mast cell or basophil origin. I shall be attaching data to this declaration showing this to be the case. But it might be helpful if I clarify the position when the original Application was filed.

At the time the experiments described in the above application were undertaken cell lines of mast cell or basophil origin were known. Moreover these cell lines were known to behave in a manner characteristic of mast cell or basophils and so were regarded as useful tools for studying immunological responses undertaken by mast cell or basophils.

Cell lines derived from mast cells or basophils and exhibiting mast cell or basophil characteristics were described at the time of the invention as homologous cell lines. (In fact, they still are.)

It therefore follows that the cell line (RBL-2H3) used by us in the above application was a homologous cell line and so a good model system for studying mast cell and basophil activity.

We have never had any reason to doubt that the RBL-2H3 cell line was not representative of other homologous cell lines and so the results derived thereby were not characteristic of mast cells or basophils. *(Indeed, were this not the case the significance of the results would be questionable and the filing of a patent would be a futile and costly exercise).* This is reflected in the initial drafting of the above application both in the main body of the text (Page 4, paragraph 2) and the original claims. I insisted, at the

time, that the Application should not be limited to the cell line used to exemplify the invention because, from my knowledge of the field, I knew other homologous cell lines could be used in the assay.

Moreover, for academic reasons, we have since confirmed that the activity of the RBL-2H3 cell line is, *de facto*, representative of a wider group of cell lines of mast cell or basophil origin. We have done this by producing novel homologous cell lines, which exemplify the invention described in the above application. We have produced two cell lines RBL J41 and RBL 2/2/C. Both possess mast cell or basophil characteristics and so respond to allergen, in the presence of IgE, by releasing cell mediators. Further, both cell lines respond in an IgE independent manner to potential allergens. (Technology and Health Care 6 (1998) 198 table 1 [RBL J41] & Eur. J. Immunol. 1996 26: 2972-2980 [RBL 2/2/C] Figure 1 Table 1).

These novel cell lines have been produced without undue burden, using essentially routine skills. It therefore follows that were it not possible to protect equivalents of the RBL 2H3 cell line a patent granting on the above application would be easily circumvented and would not provide the applicant with appropriate protection having regard to the nature of the disclosed invention.

Respectful consideration is requested.

Brigitte Helen  
Sheffield  
March 7th, 2002